JUN 0 4 2002

K021700

Section 1 – Information Required by the Safe Medical Devices Act of 1990

1.1 510(k) Summary

Date: March 13, 2002

Submitter: Animas Corporation, 590 E. Lancaster Avenue, Frazer, PA 19355

Contact: Richard R. Michelin, Vice President of Quality Assurance,
Telephone: (610)-644-8990, ext 185, Fax: (610)-644-8717,
Email: richardm@animascorp.com

Name of Device: Animas ezSerter™ Infusion Set Inserter

Common Name: Inserter

Classification Name: Introducer, Syringe Needle

Predicate Device: MiniMed Sil-Serter™ Infusion Set Insertion System

Description of the New Device: The Animas ezSerter™ Infusion Set Inserter is a simple device for automatically inserting the cannula of the Animas ezSet™ angled infusion sets subcutaneously. The inserter is composed of several molded plastic pieces and stainless steel springs. An elongated molded plastic housing acts as a handle and a guide for an internally mounted spring-loaded carrier. An opening in the proximal end of the carrier accepts and retains the handle of the introducer needle hub.

The inserter may be held in either hand. To operate the inserter, the user places a sterile infusor base into the carrier. The spring-loaded retainer locks the base in place, automatically aligning and retaining the insertion needle axis. The user then folds the front flap of the adhesive pad up under the retainer trigger to expose the introducer needle and cannula. The user draws back the carrier until it locks in the cocked position. At this stage, the sliding safety may be switched to the "locked" position to prevent the accidental release of the carrier while the inserter is positioned or the site is cleaned. The protective sleeve over the cannula is then removed.

A small fold is formed at the infusion site by pinching the skin between the thumb and finger of the free hand. After releasing the safety, the inserter is held at approximately a 30 degree angle to the surface of the skin. The proximal edge of the inserter is positioned at the edge of the skin fold with the needle is pointing towards the middle of the fold. When the release button is pressed, the carrier

springs forward, quickly and smoothly inserting the needle and cannula subcutaneously. The skin fold is released and the backing paper is removed from the front flap of the adhesive pad. The adhesive pad is then smoothed over the skin, covering the point of entry with the transparent window of the pad. The sides of the introducer needle hub are pinched together to release the introducer needle from the cannula housing; the inserter and attached needle are withdrawn. The inserter is set aside while the rear backing paper is removed and the pad is smoothed to the skin. The tubing set may then be attached to the cannula housing to allow the insulin to flow into the infusion site. The retainer button is pressed to release the introducer needle from the inserter for disposal.

Intended Use of the New Device: The Animas ezSerter™ Infusion Set Inserter is intended to aid in the insertion of Animas ezSet™ infusion sets.

This device is intended for home use and is a prescription device.

Comparision of the Technological Features of the New Device and the Predicate Device: The new device and the predicate devices are substantially similar in terms of technology. Both are spring loaded devices. The user must load the infusion set into the device, compress a spring and activate the device by pressing a trigger button.

The differences between the new device and the predicate devices do not affect the safety or effectiveness of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 0 4 2002

Animas Company
Mr. Robert Mosenkis
Responsible Third Party Official
CITECH
5200 Butler Pike
Plymouth Meetings, Pennsylvania 19462-1298

Re: K021700
Trade/Device Name: Animus ezSerter™ Infusion Set Inserter
Regulation Number: 880.6920
Regulation Name: Syringe Needle Introducer
Regulatory Class: II
Product Code: KZH
Dated: May 22, 2002
Received: May 23, 2002

Dear Mr. Mosenkis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

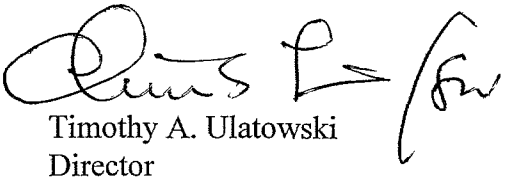
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements

of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1.3 Indications for Use Statement

510(k) Number: _____

Device Name: Animas ezSerter™ Infusion Set Inserter

Indications for Use: The Animas ezSerter™ Infusion Set Inserter is intended to aid in the insertion of the Animas ezSet™ infusion sets.

This device is intended for home use and is a prescription device.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Rebecca Cucante

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K021700